

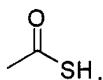
REMARKS

I. Claim Status

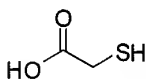
Claims 61-67 and 71-119 are currently pending. Claims 68-70 have been canceled without prejudice herein. Claims 61, 62, 64-66, 71, 73-80, 83-97, 102, and 116 have been amended herein. Those amendments are supported in the specification as originally filed. Accordingly, no new matter is added herein. Claims 61-119 stand rejected.

II. Amendments to the Specification

Applicants respectfully request that the Examiner enter the amendments to the specification noted above. Those amendments do not add new matter and simply seek to correct an inadvertent nomenclature error. In particular, thioacetic acid has the following formula:



The compound disclosed in the present specification has a different structure:



. See page 66, Scheme. One of skill in the art would recognize that the correct name for this compound is 2-mercaptoacetic acid. Therefore, Applicants request that the amendments to the specification be entered.

III. Enablement Rejections

35 U.S.C. § 112, First Paragraph Rejection of Claims 108-112 and 115

The Examiner rejected claims 108-112 and 115 under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement. Office Action at 3. Applicants respectfully traverse that rejection.

Applicants respectfully point out that although the Examiner lists several methods of treating various disorders, *see id.* a)-b), some of those methods are not encompassed within the scope of the rejected claims. For example, “a method for the modification of the fat distribution and content of animals,” is recited in claim 106, which has not been rejected. However, in order to advance prosecution, Applicants present arguments herein directed toward the enablement of all currently pending method claims.

In making this rejection, the Examiner has improperly applied the *Wands* factors, failing to consider the evidence as a whole. *See* M.P.E.P. 2164.01(a); *see also In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). In particular, the Examiner has ignored the state of the art at the time this application was filed and dismissed Applicants’ arguments presented in their December 20, 2007, Response regarding the same. Indeed, the Examiner has failed to acknowledge that “a patent need not teach, ***and preferably omits***, what is well known in the art.” M.P.E.P. § 2164.01 (emphasis added); *see also In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). Applicants respectfully maintain their position that the present specification combined with the knowledge in the art at the time the present application was filed would enable one of skill in the art to make and use the claimed invention.

Applicants respectfully submit that one of skill in the art would be aware of methods to test—without undue experimentation—whether compounds within the genus of Formula I would be effective for the various indications claimed. That knowledge can be derived from at least the disclosures of WO 99/58121 (methods for treating/preventing obesity), WO 99/58122 (methods for treating/preventing diabetes),

WO 99/58123, WO 02/03983 (methods for treating/preventing cancer), WO 02/26218 (methods for treating/preventing proliferation and skin disorders), and WO 02/43728 (methods for treating/preventing autoimmune disorders), wherein similar, but patentably distinct, compounds have been shown to exhibit a variety of biological effects via disclosed experimental techniques. Therefore, one of skill in the art would be able to make and use the presently claimed invention without undue experimentation.

It appears as though the Examiner is concerned with the burden of both making and testing compounds of Formula I: “[h]owever, *arguendo* one of ordinary skill in the art at the time of the Applicants’ invention would engage in erstwhile experimentation, would still have to determine permutations of potential compounds *before* engaging in said complex experiments and engage in vast experimentation to determine the modes of administration, levels of dosage for equally numerous compounds of formula (I).” Office Action at 5. The Examiner’s concern for the number of possible compounds and “vast experimentation” is not enough to support a *prima facie* case of non-enablement. Here again the Examiner has ignored the evidence as a whole and instead has focused on quantity rather than what was known in the art at the time the present application was filed. “Time and difficulty of experiments are not determinative if they are merely routine. Quantity of examples is only one factor that must be considered before reaching the final conclusion that undue experimentation would be required.” M.P.E.P. § 2164.06; *see also In re Wands*, 858 F.2d at 737. Because the Examiner has failed to consider what was known in the art at the time this application was filed, no *prima facie* case of enablement has been established. As a result, this rejection should be withdrawn.

35 U.S.C. § 112, First Paragraph Rejection of Claims 61-100

The Examiner rejected claims 61-100 under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement. Office Action at 6. Applicants respectfully traverse this rejection.

The Examiner has not established a *prima facie* case of non-enablement for at least the reason that the Examiner has failed to recognize that the disclosed methods of making compounds according to the Formula I “bear[] a reasonable correlation to the entire scope of the claim.” M.P.E.P. § 2164.01(b); *see also In re Fisher*, 427 F.2d 833, 839, (C.C.P.A. 1970). A key consideration for this inquiry is whether the starting materials/equipment are commercially available. *See id.* Applicants respectfully point out that a large number of fatty acids are commercially available having different chain lengths and degrees of unsaturation/substitution.

Moreover, one of skill in the art would know that the presently disclosed methods are exemplary and could be utilized with different starting materials to produce compounds within the scope of the present claims. For example, one of skill in the art would know that the glycerophosphocholine (GPC) exemplified in Example 2.2, Scheme 4 could be replaced with glycerophosphoinositol or glycerophosphoinositolglycerol to prepare PI and PG headgroups, respectively. In addition, one of skill in the art would know that Y equal to a group other than S could be achieved for example, by substituting 2-hydroxysebacic acid for 2-mercaptoacetic acid in the general Schemes 1 and 2. Applicants submit that these examples are representative, and that one of skill in the art combined with the knowledge of the art at the time of the filing of the present application, e.g., WO 01/6852, WO 99/58122, and WO 97/03663, would be

able to make and use the compounds according to claims 61-100. For at least these reasons, this rejection should be withdrawn.

35 U.S.C. § 112, First Paragraph Rejection of Claims 101-119

The Examiner rejected claims 101-119 under 35 U.S.C. § 112, first paragraph for allegedly lacking enablement. Office Action at 7. Applicants respectfully traverse this rejection.

This rejection appears to combine the two enablement rejections addressed above. As already discussed above, one of skill in the art at the time the application was filed would know how to make and use the invention. For at least the same reasons already discussed, this rejection should be withdrawn.

IV. 35 U.S.C. § 112, Second Paragraph Rejection of Claims 61-100

The Examiner rejected claims 61-100 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Office Action at 10. Applicants respectfully traverse this rejection.

Without in any way conceding the propriety of this rejection, Applicants have amended and canceled claims herein to remove the claim limitation where PHG is a -W-Linker-HG group. Accordingly, this rejection has been rendered moot and should be withdrawn.

V. Double Patenting Rejection

The Examiner provisionally rejected claims 61-119 on the grounds of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 9, 13, 20-23, 32, 33, 39-44, and 48 of copending Application No. 10/484,855.

Office Action at 11. Applicants request that the Examiner hold this rejection in abeyance until allowable subject matter is found.

VI. 102(b) Rejection

The Examiner has rejected claims 61-64, 67, 84, and 86 under 35 U.S.C. § 102(b) as allegedly being anticipated by Ruoxin et al. *J. Org. Chem.* (1993) 58:1952-1954 ("Ruoxin"). Office Action at 12. Applicants respectfully traverse this rejection.

Claim 61 has been amended herein. Those amendments find support in the present specification at, for example, page 19, line 8. In addition, *In re Wertheim* supports the proposed amendment because that court reasoned that Applicants can excise from their invention that which is of the prior art. See *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976). In view of amended claim 61, this rejection has been rendered moot and should be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: July 22, 2008

By: *Erin M. Sommers*
Erin M. Sommers
Reg. No. 60,974